Health-related quality of life in patients with osteoarthritis after total knee replacement: Factors influencing outcomes at 36 months of follow-up

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Summary

Objectives: (1) To evaluate health-related quality of life (HRQL) in patients with severe osteoarthritis (OA) undergoing total knee replacement (TKR) and (2) to identify the influence of sociodemographic, clinical, intra-operative and postoperative variables on HRQL at 36 months after TKR.

Design: Prospective study with a 36-month follow-up. Preoperative interviews were carried out with 90 in-patients. The disease-specific Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire was used to measure the health status. Sociodemographic, clinical, intra-operative degree of difficulty, in-patient and postoperative data were collected. Associations were analyzed using linear regression models.

Results: Of the 90 potentially eligible patients, 67 (54 females, mean age 74.83, standard deviation [SD] 5.57) completed follow-up assessment. There were significant differences between preoperative and postoperative WOMAC pain, stiffness and function scores ($P < 0.001$, $P = 0.005$ and $P < 0.001$, respectively). Variables retained in each of the models explained between 15% and 23% ($R^2$ adjusted) of the variability of each WOMAC dimension. Higher preoperative WOMAC scores were associated with greater postoperative improvement ($P < 0.001$). Chronic musculoskeletal pain unrelated to knee OA was associated with higher WOMAC pain, stiffness and function dimension scores ($P = 0.004$, $P = 0.029$ and $P = 0.005$, respectively). Severe (Class III) obesity (body mass index [BMI] 35–39.9) was associated with more pain ($P = 0.049$).

Conclusions: In patients with severe OA, HRQL significantly improved at 36 months after TKR, especially in the pain dimension. Lower preoperative WOMAC scores, chronic pain unrelated to knee OA, and severe obesity negatively influenced postoperative WOMAC scores. This disease-specific questionnaire may help to identify patients at increased risk of negative outcomes after surgery.

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Introduction

In developed countries, increased life expectancy has resulted in an aging population, which, together with a tendency to greater overweight, has led to changes in morbidity which, in the case of musculoskeletal diseases, has meant an increase in health-related quality of life (HRQL) and therefore the demand for lower-limb joint replacement is increasing. Standardized specific measures centered on issues associated with a particular health condition or diagnosis are used to estimate the severity of symptoms and evaluate outcomes. In knee OA, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC Likert [LK] 3.0) is recommended for monitoring functional outcomes in total knee replacement (TKR).

TKR is effective in improving disability and the HRQL of sufferers. However, sociodemographic or clinical characteristics such as gender or obesity, and surgical factors may influence outcomes. Kane et al. in a recent evidence report on TKR state that in observing outcomes there are few reports that use multivariate analysis (only 12 out of 69 studies analyzed) to determine the influence of sociodemographic and clinical variables on change in the functional status of the patients. Thus, there remains a lack of evidence and difficulties in establishing the criteria which define the ideal moment for the placement of TKR.

The follow-up of patients undergoing TKR is usually short term, with less studies of medium- or long-term results.
(between 2 and 5 years). Although most reports suggest that the greatest changes in function and pain occur during the first 3–6 months after surgery, prosthetic failures and complications13, mainly occur more than 2 years after the intervention1,11.

The objectives of this study were: (1) to evaluate HRQL in patients with severe OA undergoing TKR and (2) to identify the influence of sociodemographic, clinical, intra-operative and postoperative variables on HRQL at 36 months after TKR.

Methods

Setting

A prospective 36-month study was carried out in the Rheumatology and Orthopaedic Surgery (Knee Unit) Services of the Hospital Provincial (HCP), Barcelona (Spain), an urban tertiary care center. Participants were enrolled between November 2000 and December 2001. The study received approval from the hospital ethics committee.

Participants

Consecutive patients of all ages admitted to the Knee Unit for primary TKR with a diagnosis of knee OA grade IV (according to Kellgren and Lawrence criteria)12 agreed to participate in the study and gave informed consent. Exclusion criteria were functional illiteracy or psychopathology severe enough that the patient could not participate fully in study procedures.

Patients who agreed to participate were informed that at 36 months they would need to attend the hospital for another interview to determine the outcome of the TKR and would be reminded by telephone or letter.

All patients received TKR. Surgical procedures and all care and treatment, including rehabilitation, were standardized according to hospital protocols13. All patients were fitted with a standard (non-constrained) prosthesis. At discharge, all patients received a booklet with advice on the care of the wound, signs of possible complications and rehabilitation exercises.

Variables Determined

Patients were interviewed on the day prior to surgery (baseline).

(1) Self-reported health status was measured by the Spanish version of the WOMAC (LK 3.0) questionnaire14, which contains three dimensions: pain, stiffness, and function. These dimensions produce scores of 0–20, 0–8, and 0–68, respectively, with higher scores indicating more pain, stiffness, and reduced physical function9,14.

Independent researcher 1 was present to provide aid, if necessary, for patients answering the questionnaire.

(2) A structured questionnaire collected information on:

(a) sociodemographic (age, gender) and clinical (disease duration [since diagnosis in years]; (b) chronic musculoskeletal pain unrelated to knee OA determined by the question “Could you tell us whether you have any other rheumatic pain, in addition to that of your knee” [yes/no]; (c) number of pre-existing comorbidities at baseline [self-reported]; (d) BMI (obtained by measurement in the hospital) (class 0: <25 kg/m², class I: 25–29.9 kg/m², class II: 30–34.9 kg/m², class III: 35–39.9 kg/m², class IV: >40 kg/m² [Ref. 15]); (e) prior prostheses [yes/no]) data. These data were collected by independent researcher 1.

(3) Medical records provided information on:

(a) intra-operative surgical data; (b) in-patient medical data; and (c) postoperative medical data. These data were collected by independent researcher 2.

(b) In-patient clinical data included: number and type of in-hospital complications before discharge (problem healing of surgical wound [yes/no], signs of deep venous thrombosis [DVT] [yes/no], immediate infection [yes/no]), ambulatory status at discharge (climbing and descending stairs [yes/no]), correct alignment of lower limb (deviations in the antero-posterior axis inferior to 3°/goniometer) by long-leg coronal X-rays (yes/no) and blood loss requiring transfusion (yes/no).

(c) Postoperative clinical data included: number and type of complications after discharge (deformity of the lower limb, dislocation of the TKR [femoral, patellar, tibial, femoropatellar], infection, pain, septic or aseptic loosening, extensor muscle failure, deep DVT and others [yes/no]).

(4) The length of hospital stay in days was also collected.

Assessment Intervals

Sociodemographic and medical data were collected at baseline. HRQL was evaluated at baseline and at 36 months. Intra-operative surgical and in-patient clinical data were collected at discharge. Postoperative clinical data were collected at 36 months.

The follow-up interviews were completed in the Rheumatology service outpatient clinic by independent researcher 1.

Data Analysis

Accepting an alpha risk of 0.05 and beta risk of 0.20 in a bilateral contrast, 65 patients were needed to detect
a finally difference $\geq 10\%$ between the mean pre- and post-operative scores for the physical function and pain dimensions of the WOMAC questionnaire, which was judged to be a clinically important difference. A common standard deviation (SD) of 6 was assumed. The sample was overestimated by 20% to allow for possible losses.

A descriptive analysis was performed using univariate frequency tabulation for categorical variables or mean values and SD for continuous variables.

The Student’s t test (paired samples) was used to evaluate the differences between mean scores at baseline and 36 months in the WOMAC pain, stiffness and function dimensions. Effect size (ES) was calculated for the different outcome measures using the formula: ES = mean change/SD of pre-intervention (baseline) results. To observe whether the baseline scores influenced changes at 36 months, patients were divided into two groups according to whether their initial scores for the WOMAC pain and function dimensions were above or below the mean.

Multiple linear regression models were used to analyze the influence of sociodemographic, clinical, intra-operative surgical, in-patient and postoperative clinical variables (independent variables) on WOMAC scores at 36 months (dependent variables).

Separate regression models were constructed for the three WOMAC dimensions. The selection criterion of variables for inclusion was forward-stepwise with an entrance criterion of $P < 0.05$ and an exit criterion of $P > 0.10$. In addition, because age, gender and the number of comorbidities were considered to be potential influencing variables they were introduced into the final models. However, coefficients for these variables were non-significant and they were excluded. Residual plots and standard diagnostics were used to check that the model assumptions were verified. The results of the models are presented using adjusted $R^2$. The CI was established at 95%. A value of $P < 0.05$ was considered statistically significant. Statistical analyses were performed using SPSS 12.0 for Windows.

Results

Ninety patients (81% females, $n = 73$), 19% males ($n = 17$) were eligible for inclusion and of these two refused to participate. Eight patients (8.8%) were lost to follow-up (death of unknown causes in one patient and seven could not be contacted after surgery). Thirteen patients (14.4%) underwent contralateral knee replacement during the follow-up and were excluded from the analysis. The remaining 67 patients completed follow-up data and were included in the analysis. A logistic regression analysis using the dependent variable participation = 1 and non-participation = 0 showed no statistically significant differences in baseline characteristics between the 67 completers and the 23 non-completers (data not shown).

Table I summarizes the main patient characteristics. The average age was 74.83 (SD 5.57) years and 81% ($n = 54$) were females. Sixty percent ($n = 40$) presented chronic musculoskeletal pain unrelated to knee OA. All patients presented one or more medical comorbidities (mean 2.47, SD 1.13), including hypertension (56%), pulmonary disease (13%), cardiovascular disease (12%) and diabetes (12%). Seven patients had overweight, 52 obesity and 8 severe obesity.

With respect to the variables of surgical difficulty, only one patient needed an approach requiring osteotomy of the tibial tuberosity. Ninety-two percent ($n = 62$) of patients were operated by a senior surgeon and in 61% ($n = 41$), the surgical time was $> 105\text{ min}$. Thirty-seven percent ($n = 25$) had no IOD (grade 1) while in the remainder ($n = 42$) the degree of IOD was low (grade 1).

The main in-patient complication was problem healing of the surgical wound ($n = 5$). All patients had correct alignment of the lower limb. The mean length of hospital stay was 6.75 days (SD 1.27). Two patients reported hospital admission during the 36-month follow-up (one debridement 15 days after TKR and one patellectomy due to pain at 18 months, both in the operated knee) and six presented pain in the operated knee.

WOMAC scores at baseline and 36 months are shown in Table II (first and second columns). The three WOMAC scales were normalized to a 0–100 scale for each separate WOMAC dimension, where 0 represents the best and 100 the worse health status. We found significant improvements in the three WOMAC dimensions (mean difference [MD] between baseline and 36-month follow-up), as shown in the third, fourth and fifth (P values of the improvement) columns of Table II. The ES is also shown in Table II in standardized units (sixth column) and represents a percentage of improvement of 54% for pain, 41% for stiffness and 31% for function.

However, 7 patients reported no improvement in postoperative pain scores, 15 in postoperative stiffness scores and 7 in postoperative function. At baseline, these patients presented significantly lower WOMAC scores than patients who improved after TKR ($P = 0.001$, $P = 0.014$ and $P = 0.001$ for pain, stiffness and function, respectively).

Likewise, patients who presented baseline scores above the median for the WOMAC pain and function dimensions showed greater improvement at 36 months than patients with scores below the median. Thus, at 36 months, the mean WOMAC pain dimension score fell from 57.94 (SD 7.19) to 24.56 (SD 16.71), $P < 0.001$, and the mean WOMAC function dimension score from 66.85 (SD 4.28) to 36.80 (SD 15.88), $P < 0.001$. In patients with baseline
scores below the median, the mean WOMAC pain dimension score fell from 37.37 (SD 9.33) to 20.78 (SD 19.24), \( P = 0.005 \), and the mean WOMAC function dimension score from 41.27 (SD 13.61) to 32.28 (SD 19.82), \( P = 0.027 \). At 36 months, the two groups presented similar scores in the WOMAC dimensions.

Table III shows the sociodemographic and clinical variables which were independently significant in the multiple linear regression analysis. The variables retained in each of the models explained between 15% and 23% (\( R^2 \) adjusted) of the variability of each WOMAC dimension.

Chronic musculoskeletal pain unrelated to knee OA was associated with higher scores in the WOMAC pain, stiffness and function dimensions (\( P = 0.004 \), \( P = 0.029 \) and \( P = 0.005 \), respectively). Severe (Class III) obesity (BMI 35–39.9 kg/m\(^2\)) was associated with more pain (\( P = 0.049 \)).

**Discussion**

At 36 months, TKR produced a significant reduction in WOMAC dimension scores, with the pain dimension showing the greatest improvement. Preoperative WOMAC scores were the best predictor of postoperative improvement.

Previous series, although with a follow-up of between 6 and 24 months, reported similar improvements in HRQL in patients undergoing TKR\(^1\)\(^–\)\(^6\),\(^11\)\(^–\)\(^24\) (for WOMAC studies the mean ES for 0–2 years of follow-up is 1.62\(^11\). Jones et al.\(^25\), Mahomed et al.\(^26\) and March et al.\(^23\) also noted a comparatively greater reduction in the WOMAC pain dimension in patients after TKR, with similar mean scores to our group. This may be because, in elderly people, pain is more likely to improve than overall function, which decreases with age\(^25\).

We did not find that age or gender affected TKR outcomes in terms of HRQL similar to other reports\(^24\),\(^26\),\(^27\), although the make up of our sample did not allow meaningful analysis of these aspects.

We found that the preoperative health status influenced postoperative outcomes, as reported by other studies\(^5\),\(^28\),\(^29\). Patients with higher preoperative WOMAC scores had greater postsurgical improvement at 36 months. Rissanen et al.\(^29\) found that patients with the worst preoperative HRQL gained most from the operation in a 2-year follow-up study that used the Nottingham Health Profile and the 15D, a 15 dimensional HRQL measure. In their revision, Ethgen et al.\(^5\) reported similar findings and commented that patients with negative preoperative HRQL are more likely to experience greater improvement. Fortin et al. in an observational cohort study of patients undergoing either total hip or knee replacement showed that patients with negative preoperative function and pain did not improve postoperatively to the level achieved by those with higher preoperative function.\(^28\) However, their results show that patients with greater deterioration of the knee, although presenting improvements after surgery, were far from achieving values similar to the reference population. The authors state in their conclusions that “surgery performed later in the natural history of functional decline due to OA of the knee results in negative postoperative functional status”. This suggests that different

The three WOMAC scales were normalized to a 0–100 scale for each separate WOMAC dimension, where 0 represents the best and 100 the worst health status.

**Table II**

<table>
<thead>
<tr>
<th>WOMAC</th>
<th>Baseline mean (SD)</th>
<th>36 Months mean (SD)</th>
<th>t test (paired samples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>50.57 (12.73)</td>
<td>23.21 (17.57)</td>
<td>27.36 (21.66–33.06)</td>
</tr>
<tr>
<td>Stiffness</td>
<td>31.84 (23.32)</td>
<td>18.89 (20.31)</td>
<td>12.95 (3.92–21.97)</td>
</tr>
<tr>
<td>Function</td>
<td>54.31 (16.28)</td>
<td>34.59 (17.90)</td>
<td>19.72 (13.51–25.92)</td>
</tr>
</tbody>
</table>

The coefficients of regression models indicate if an increase in the independent variables is related to an increase (worse) [positive coefficient] or decrease (better) [negative coefficient] in WOMAC dimensions. \( R^2 \) adjusted is the proportion of variance in the dependent variable explained by the relevant independent variables shown. The three WOMAC scales were normalized to a 0–100 scale for each separate WOMAC dimension, where 0 represents the best and 100 the worst health status.
reports present their results from different perspectives rather than having widely differing results in themselves. However, as overall functional decline is common in the elderly, it seems reasonable to think that subjects with greater disability or pain would have a greater appreciation of changes in these parameters after TKR.

Our study also illustrates the substantial independent impact of chronic musculoskeletal pain not related to knee OA on joint replacement HRQL outcomes. Reports have noted that pain is frequently associated with worse quality of life. If TKR is indicated to recover function in patients with untreatable pain and/or severe disability when conservative treatment does not yield acceptable results. Chronic pain is usually associated with disability, emotional alterations and a bad response to treatment. It seems logical to think that in patients undergoing TKR the presence of chronic rheumatic pain elsewhere in the body could influence both the patient’s capacity of recovery post-surgery and the fulfillment of the patient’s expectations of the surgery in terms of a better quality of life. In a recent Spanish study, Escobar et al. found that low back pain was a good predictor of worse outcomes in the WOMAC dimensions after TKR and that similar results have been found for hip replacements. The authors suggest that “the isolated influence of this variable on WOMAC could be controversial given that the WOMAC questionnaire seems to capture more than just knee or hip pain or dysfunction and is influenced by the presence of low back pain”.

Severe obesity, but not obesity or overweight, was significantly associated with worsened pain. Several studies have found similar results with respect to severe obesity and chronic pain elsewhere in the body could influence the outcomes of TKR. At a mean of approximately 7 years postoperatively, the obese group had a significantly lower rate of improvement than the non-obese group (measured by Knee Society scores). Other reports have found that obesity not only complicates the technical aspects of the surgery and immediate postoperative period, but may also be an impediment to achieving autonomy and may affect the durability of the prosthesis. Some studies have found that obese patients have a higher percent of revisions due to loosening of the prosthesis compared to non-obese patients. In contrast, Kane et al. found that obesity was not a significant independent variable in the regression analysis explained between 14.5% and 22.9% of the variability (Table III). It may be that a study with a much larger number of patients, for which we are currently recruiting, would reveal other significant variables. In any case, these results clearly show the multifactorial nature of the health status of these patients, and suggest that other variables, possibly including some not contemplated in the present study, have a greater or lesser influence in these patients.

Our patients had a low frequency of intra-operative and postoperative difficulties. This could be regarded as a good indirect quality control of the surgical procedure. However, the low frequency of difficulties meant that it was not possible to estimate the influence of the grading of IODs on the results. A larger group of patients, with more complicated cases, including revisions, would be necessary to test the validity of this proposed index. We are currently recruiting patients for inclusion in this larger study. Kane et al. reported that complications, as in our study, are defined by each investigator and found low rates of complications. This makes comparison between series difficult. Homogenous criteria should be developed to measure IODs and complications during the follow-up of TKR patients.

The present study had various limitations. The relatively small number of patients included limited the analysis of perioperative and postoperative events. All patients were selected from a tertiary referral center and the results may not be applicable to other types of center. Patients undergoing a contralateral TKR (14%) were excluded as we believed this subgroup could have distorted the results. This could have biased the results, as these patients might represent a subgroup with different outcomes, depending on the time passed since the contralateral TKR. The low proportion of males and the narrow age range of our patients limited the usefulness of the results with respect to age and gender, although the patients were fairly typical in these respects of the majority of patients undergoing TKR. In addition, we did not analyze possible confounding variables, including the number of rehabilitation sessions during the first months after surgery, social support and medical treatment and the appropriateness of joint replacement. However, to our knowledge, the degree of IOD has not previously been studied in this group of patients. In addition, a well-controlled study from a single center allows better control of variables and may provide additional evidence on the independent predictive features such as obesity. Finally, a difference >10% between the mean pre- and postoperative scores for the physical function and pain dimensions of the WOMAC questionnaire was judged to be a clinically important difference in this study. Although a 10% difference is often accepted as reasonable for pharmacological treatment, it is not certain that this is true for surgical treatments. However, we believe that, although small, this difference is more demanding with respect to the calculation of the sample size.

Other studies have reported similar patient characteristics with respect to the preoperative state and the improvements obtained after TKR. This suggests that our findings, although from a single center, could be applicable to other populations.

In summary, we found that, in patients with severe OA, the health status significantly improved at 36 months after TKR, especially in the WOMAC pain dimension. Lower preoperative WOMAC scores, chronic pain unrelated to knee OA and severe obesity negatively influenced postoperative WOMAC scores. This disease-specific questionnaire may help to identify patients at increased risk of negative outcomes after surgery.

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References


